K080183

MAR 25 2008

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

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Contact Person: Dimitris Demirtzoglou

Date Prepared: January 23, 2008

2) Device name

Proprietary name:

a. Control Set DAT I
b. Control Set DAT II
c. Control Set DAT III
d. Control Set Amphetamine 1000
e. Control Set Amphetamine 500

3) Regulatory information

Applicable to each of the devices.

Product Code:	DIF
Product Code Name:	Drug Mixture Control Materials
Device Class:	Class I
Classification panel:	Clinical Toxicology
C.F.R section:	862.3280 - Clinical Toxicology Control Material

4) Predicate devices

We claim substantial equivalence for each of the devices to the currently marketed TDM Control Set (K070200).

5) Device Description

Control Set DAT I

Control Set DAT I is prepared by the quantitative addition of drug or drug metabolite to drug-free human urine. Preservative and stabilizer are added to maintain product integrity.

Control Set DAT I contains a mixture of 10 different drugs. Drug concentrations in are verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at ± 25% of the assay cutoff.

Drug	Assay Cutoff	Target Concentration (ng/mL)	
		PreciNeg	PreciPos
Amphetamines (d-methamphetamine)	500	375	625
Barbiturates (secobarbital)	200	150	250
Benzodiazepines (nordiazepam)	300	225	375
Cannabinoids (Δ9 THC-COOH)	50	37.5	62.5
Cocaine (benzoylecgonine)	150	113	188
Methadone (dl-methadone)	300	225	375
Methaqualone (methaqualone)	300	225	375
Opiates (d-morphine)	2000	1500	2500
PCP (phencyclidine)	25	18.8	31.3
Propoxyphene (propoxyphene)	300	225	375

Control Set DAT II

Control Set DAT II is prepared by the quantitative addition of drug or drug metabolite to drug-free human urine. Preservative and stabilizer are added to maintain product integrity.

Control Set DAT II contains a mixture of 4 different drugs. Drug concentrations in Control Set DAT II are verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at ± 25% of the assay cutoff.

Drug	Assay Cutoff	Target Concentration (ng/mL)	
		PreciNeg	PreciPos
Amphetamines (d-methamphetamine)	300	225	375
Benzodiazepines (nordiazepam)	100	75	125
Cannabinoids (Δ9 THC-COOH)	20	15	25
Opiates (d-morphine)	300	225	375

Continued on next page

5) Device Description (continued)

Control Set DAT III

Control Set DAT III is prepared by the quantitative addition of drug or drug metabolite to drug-free human urine. Preservative and stabilizer are added to maintain product integrity.

Control Set DAT III contains a mixture of 4 different drugs. Drug concentrations in Control Set DAT II are verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at ± 25% of the assay cutoff.

Drug	Assay Cutoff	Target Concentration (ng/mL)	
		PreciNeg	PreciPos
Amphetamines (d-methamphetamine)	1000	750	1250
Benzodiazepines (nordiazepam)	200	150	250
Cannabinoids (Δ9 THC-COOH)	100	75	125
Cocaine (benzoylecgonine)	300	225	375

Control Set Amphetamine 1000

Control Set Amphetamine 1000 is prepared by the quantitative addition of d-amphetamine to drug-free human urine. Preservative is added to maintain product integrity.

Drug concentrations in Control Set Amphetamine 1000 are verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at ± 25% of the assay cutoff.

Drug	Assay Cutoff	Target Concentration (ng/mL)	
		PreciNeg	PreciPos
Amphetamines (d-	1000	750	1250

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5) Device Description (continued)

Control Set Amphetamine 500

Control Set Amphetamine 500 is prepared by the quantitative addition of d-amphetamine to drug-free human urine. Preservative is added to maintain product integrity.

Drug concentrations in Control Set Amphetamine 500 are verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at ± 25% of the assay cutoff.

Drug	Assay Cutoff	Target Concentration (ng/mL)	
		PreciNeg	PreciPos
Amphetamines (d-	500	375	625

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6.) Intended Use

Control Set DAT I

The Control Set DAT I is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.
This product cannot be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines **cobas c** pack (AMPS). Refer to the package insert or method sheet for information regarding the controls appropriate for use with these assays.

Control Set DAT II

The Control Set DAT II is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.
This product cannot be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines cobas c pack (AMPS). Refer to the package insert or method sheet for information regarding the controls appropriate for use with these assays.

Control Set DAT III

The Control Set DAT III is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.
This product cannot be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines **cobas c** pack (AMPS). Refer to the package insert or method sheet for information regarding the controls appropriate for use with these assays.

Control Set Amphetamine 1000

The Control Set Amphetamine 1000 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines cobas c pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.

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6.) Intended Use (continued)

Control Set Amphetamine 500

The Control Set Amphetamine 500 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines **cobas c** pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.

7.) Comparison to the Predicate Device

Below the similarities and differences between the Control Set DAT I, Control Set DAT II, Control Set DAT III, Control Set Amphetamine 1000, Control Set Amphetamine 500, and its predicate device TDM Control Set (K070200) are presented.

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510(k) Summary, Continued

7.) Comparison to the Predicate Device
(continued)

	New Device	Predicate Device
Item	Control Set DAT I	TDM Control Set
Intended Use	The Control Set DAT I is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers. This product cannot be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines **cobas c** pack (AMPS). Refer to the package insert or method sheet for information regarding the controls appropriate for use with these assays.	The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.
Analytes	• Amphetamines (d-methamphetamine) • Barbiturates (secobarbital) • Benzodiazepines (nordiazepam) • Cannabinoids (Δ9 THC-COOH) • Cocaine (benzoylecgonine) • Methadone (dl-methadone) • Methaqualone (methaqualone) • Opiates (d-morphine) • PCP (phencyclidine) • Propoxyphene (propoxyphene)	• Acetaminophen • Amikacin • Carbamazepine • Digoxin • Gentamicin • Lidocaine • N-acetylprocainamide • Phenobarbital • Phenytoin • Primidone • Procainamide • Quinidine • Salicylate • Theophylline • Tobramycin • Valproic acid • Vancomycin.
Form	Liquid	Liquid
Traceability	GC/MS[1]	USP Standards
Matrix	Human urine based	Human serum based
Number of Levels	2	3

[1]Gas Chromatography/Mass Spectrometry

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7.) Comparison to the Predicate Device
(continued)

	New Device	Predicate Device
Item	Control Set DAT II	TDM Control Set
Intended Use	The Control Set DAT II is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers. This product cannot be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines cobas c pack (AMPS). Refer to the package insert or method sheet for information regarding the controls appropriate for use with these assays.	The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.
Analytes	• Amphetamines (d-methamphetamine) • Benzodiazepines (nordiazepam) • Cannabinoids (Δ9 THC-COOH) • Opiates (d-morphine)	• Acetaminophen • Amikacin • Carbamazepine • Digoxin • Gentamicin • Lidocaine • N-acetylprocainamide • Phenobarbital • Phenytoin • Primidone • Procainamide • Quinidine • Salicylate • Theophylline • Tobramycin • Valproic acid • Vancomycin.
Form	Liquid	Liquid
Traceability	GC/MS[1]	USP Standards
Matrix	Human urine based	Human serum based
Number of Levels	2	3

[1]Gas Chromatography/Mass Spectrometry

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7.) Comparison to the Predicate Device
(continued)

	New Device	Predicate Device
Item	Control Set DAT III	TDM Control Set
Intended Use	The Control Set DAT III is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers. This product cannot be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines cobas c pack (AMPS). Refer to the package insert or method sheet for information regarding the controls appropriate for use with these assays.	The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.
Analytes	• Amphetamines (d-methamphetamine) • Benzodiazepines (nordiazepam) • Cannabinoids (Δ9 THC-COOH) • Cocaine (benzoylecgonine)	• Acetaminophen • Amikacin • Carbamazepine • Digoxin • Gentamicin • Lidocaine • N-acetylprocainamide • Phenobarbital • Phenytoin • Primidone • Procainamide • Quinidine • Salicylate • Theophylline • Tobramycin • Valproic acid • Vancomycin.
Form	Liquid	Liquid
Traceability	GC/MS[1]	USP Standards
Matrix	Human urine based	Human serum based
Number of Levels	2	3

[1]Gas Chromatography/Mass Spectrometry

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510(k) Summary, Continued

7.) Comparison to the Predicate Device
(continued)

	New Device	Predicate Device
Item	Control Set Amphetamine 1000	TDM Control Set
Intended Use	The Control Set Amphetamine 1000 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines cobas c pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.	The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.
Analytes	• Amphetamines (d-amphetamine)	• Acetaminophen • Amikacin • Carbamazepine • Digoxin • Gentamicin • Lidocaine • N-acetylprocainamide • Phenobarbital • Phenytoin • Primidone • Procainamide • Quinidine • Salicylate • Theophylline • Tobramycin • Valproic acid • Vancomycin.
Form	Liquid	Liquid
Traceability	GC/MS[1]	USP Standards
Matrix	Human urine based	Human serum based
Number of Levels	2	3

[1]Gas Chromatography/Mass Spectrometry

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7.) Comparison to the Predicate Device
(continued)

	New Device	Predicate Device
Item	Control Set Amphetamine 500	TDM Control Set
Intended Use	The Control Set Amphetamine 500 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines **cobas c** pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.	The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.
Analytes	• Amphetamines (d-amphetamine)	• Acetaminophen • Amikacin • Carbamazepine • Digoxin • Gentamicin • Lidocaine • N-acetylprocainamide • Phenobarbital • Phenytoin • Primidone • Procainamide • Quinidine • Salicylate • Theophylline • Tobramycin • Valproic acid • Vancomycin.
Form	Liquid	Liquid
Traceability	GC/MS[1]	USP Standards
Matrix	Human urine based	Human serum based
Number of Levels	2	3

[1]Gas Chromatography/Mass Spectrometry

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Roche Diagnostics Corp.
c/o Mr. Dimitris Demirtzoglou
Regulatory Affairs Consultant
9115 Hague Road, P.O. Box 50416
Indianapolis, IN 46250

MAR 25 2008

Re: k080183
Trade Name: Control Set Dat I, Control Set Dat II, Control Set Dat III, Control Set Amphetamine 1000, Control Set Amphetamine 500
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I, reserved
Product Codes: DIF
Dated: January 23, 2008
Received: January 25, 2008

Dear Mr. Demirtzoglou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k080183

Device Name: Control Set DAT I, Control Set DAT II, Control Set DAT III, Control Set Amphetamine 1000, Control Set Amphetamine 500

Indication For Use:

The Control Set DAT I is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers as indicated in the System Information.

The Control Set DAT II is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers as indicated in the System Information.

The Control Set DAT III is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers as indicated in the System Information.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k080183

None of these above named products can be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines cobas c pack (AMPS). The package insert or method sheet for information regarding the controls has appropriate instructions for use with these assays.

The Control Set Amphetamine 1000 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines cobas c pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.

The Control Set Amphetamine 500 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines **cobas c** pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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